K031996

ABT Advanced Back Technologies, Inc.

510(K) Summary

JUL 2 3 2004

Company Name:	Advanced Back Technologies, Inc. 227 Jackson Avenue Syosset, NY 11791
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Date Prepared:	July 13, 2004
Trade Name:	Extentrac Elite
Common Name:	Traction Equipment, Powered
Class and Reference:	Class II (21 CFR SECTION 890.5900)
Product Code:	89ITH
Panel Code:	87OR

Substantial Equivalent to the following Predicate Devices:

- Extentrac, 510(k) Number-K890021
- Vax-D Therapeutic table – K951622
- 3D ActiveTrac, 510(k) number K001712
- Galaxy 900 HS chiropractic table [Class 1 exempt]
- Galaxy McManis Mobile-Trac Hydraulically-Controlled Table (see page 12).

Device Description:
The Extentrac Elite is a multifunctional traction table that incorporates two traction force generators to supply 'powered' traction during horizontal patient positioning while offering 'gravitational' traction and selective patient positioning during treatment into flexion, axial, extension, and lateral flexion.

The device consists of two main assemblies:

1. A rectangular base platform, which provides the support for the rotating patient upper support platform.
2. A rotating cushioned patient platform (upper top section) consisting of three separate support cushions attached to the sub-support frame. It is pivotally connected at its approximate center of gravity with the top end of the rectangular base platform. This provides the rotational capability to effect vertical gravity

treatment protocols and positions the rotating patient platform assembly in the horizontal plane for administrating decompression /distraction protocols utilizing the power features in the lumbar and leg assembly respectively.

The rotating patient platform assembly consists of 1. Underarm/supports with integral handgrips containing the patient controls, 2. Lumbar back support cushion assembly (convex shaped), 3. Leg Support Assembly, 4. Upper Torso Support Cushion Assembly, 5. Overhead Rear Gripping Bar.

This patient platform and the attached assemblies measures 80 inches long with the power traction leg assembly un-extended and 89 inches fully extended. The manual leg assembly range is 12 inches. The total vertical retracted height of the device is 84 inches and the height extended is 92 inches. The width of the rectangular base is 35 inches.

Two hydraulic cylinders internal to the right and left side telescoping columns on the rectangular base platform raise and lower the height of the moving assembly by 12 inches.

The leg assembly distractive range is 9 inches (power)
The lumbar assembly distractive range is 6 inches (power)

Maximum weight capacity is 300 lbs.

All of the devices movements are powered by hydraulic actuators. The actuators position the device and all assemblies with the use of positioning sensing potentiometers for exact input of data to the PLC to coordinate and sequence all of the devices movements. The traction/distractive forces applied are through hydraulic driven assemblies with load cells to accurately monitor pounds of force applied throughout the treatment cycle.

The device is controlled by the practitioner with following:

1. Remote Control Keypad
2. Computer Flat Screen Monitor and Mouse
3. Control Bar Switches on Leg Assembly
4. Lumbar Side Control Panel
5. Power Control Panel

Patients may control gravity traction vertical procedures by utilizing handgrip switches or overhead rear gripping bar switches. These switches control the patient platform rotation and the lumbar extension of the lumbar cushion.

Patients do not have the ability to utilize any of the power traction features of either the lumbar or leg assemblies. Operation of the patient switches may be deactivated by the practitioner at any time.

The level of device risk has been evaluated to be minimum, as numerous safety features have effectively mitigated any hazards.

Intended Use:

Extentrac consists of rotating patient platform and two separate traction force generators. It is designed to exert a therapeutic distractive force on the patient's spine through 'gravitational' or 'motorized' means as required to relieve pressure on anatomical structures that may be causing pain. It produces the forces and positions required to cause decompression of the intervertrebral discs, that is, unloading due to distraction and positioning.

Indications for Use:

Conditions that may be treated include localized low back pain or peripheral radiation / sciatica due to:

- Protruding or herniated intervertebral discs
- Acute facet problems
- Degenerative disc disease

Federal law restricts this device to sale on or by the order of a licensed practitioner.

Device Testing:

Following initial submission of the 510(k) cited above, the ABT Extentrac Elite device was tested and certified to be in compliance with IEC 601-1-1 Electrical Medical Equipment, General Requirements for Safety, and IEC 601-1-2 Electromagnetic Compatibility, per Underwriters Laboratories (UL) file E246377.

Revisions of the device required to meet UL certifications involved minor adjustments to mechanical and electrical configuration; they were primarily related to shielding to meet the EMC standard. None of the changes impacted the Substantial Equivalence or Safety and Effectiveness of the device as enumerated in the 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2004

David F. Cuccia
President
Advanced Back Technologies, Inc.
227 Jackson Avenue
Syosset, New York 11791

Re: K031996
Trade/Device Name: Extentrac Elite
Regulation Number: 21 CFR 890.5900
Regulation Name: Powered traction equipment
Regulatory Class: II
Product Code: ITH
Dated: June 11, 2004
Received: June 16, 2004

Dear Mr.Cuccia :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K031996

Device Name: Extentrac Elite

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Prescription Use X
(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K031996